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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/672,072  | 09/25/2003  | Clive Elson          | CGR-013CP3          | 4689             |
| 959   | 7590        | 07/15/2004           | EXAMINER            |                  |
| LAHIVE & COCKFIELD, LLP.<br>28 STATE STREET<br>BOSTON, MA 02109 |             |                      | CRANE, LAWRENCE E   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1623                |                  |
| DATE MAILED: 07/15/2004   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/672,072 | <b>Applicant(s)</b><br>ELSON ET AL. |  |
|                              | <b>Examiner</b><br>L. E. Crane       | <b>Art Unit</b><br>1623             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

No claims have been cancelled, no claims have been amended, the Figures have been amended, and no new claims have been added as per the preliminary amendment filed March 5, 2004. No Information Disclosure Statements (IDSs) have been filed as of the mailing date of this Office action.

Claims **1-42** remain in the case.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims **1-17**, drawn to a method of inhibiting tissue adhesions by application of a N,O-carboxymethylchitosan coating, classified in Class 514, subclass 055.000.

II. Claims **18-27**, drawn to a method of obtaining a population of cells wherein the subpopulation of substrate-dependent cells is minimized by growing the cells in a culture modified by addition of N,O-carboxymethylchitosan, classified in Class 435, subclasses 001.000 and 325.000 and Class 536, subclass 020.000.

III. Claims **28-42**, drawn to a method of inhibiting attachment of inflammatory cells or proteins to a medical device comprising coating said device with N,O-carboxymethylchitosan, classified in Class 514, subclass 055.000.

The inventions are distinct, each from the other because of the following reasons:

Inventions **I and II** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the two inventions have different functions, the first invention being directed to a method of inhibiting tissue adhesions by application of a N,O-carboxymethylchitosan coating, and the second invention being directed to a method of obtaining a population of cells wherein the subpopulation of substrate-dependent cells is minimized by growing the cells in a culture modified by addition of N,O-carboxymethylchitosan.

Inventions **I and III** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they

have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the two inventions have different functions, the first invention being directed to a method of inhibiting tissue adhesions by application of a N,O-carboxymethylchitosan coating, and the second invention being directed to a method of inhibiting attachment of inflammatory cells or proteins to a medical device comprising coating said device with N,O-carboxymethylchitosan.

Inventions **II and III** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the two inventions have different functions, the first invention being directed to a method of obtaining a population of cells wherein the subpopulation of substrate-dependent cells is minimized by growing the cells in a culture modified by addition of N,O-carboxymethylchitosan, and the second invention being directed to a method of inhibiting attachment of inflammatory cells or proteins to a medical device comprising coating said device with N,O-carboxymethylchitosan.

Because these inventions are distinct for the reasons given above and 1) have acquired a separate status in the art as shown by their divergent classification, 2) have acquired a separate status in the art because of their recognized divergent subject matter, and 3) the search required for each of Groups **I and III** are not required for Group **II**, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Ralph A. Loren on June 18, 2004 a provisional election was made with traverse to prosecute the invention of Group **III**, claims **28-42**. Affirmation of this election must be made by applicant in responding to this Office action. Claims **1-27** are withdrawn from further consideration by the Examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. §1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the

currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(h).

Claims **28-42** remain under examination in the case.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thompson*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. §§1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with the application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, an registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **28-42** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-4** of U.S. Patent No. **6,645,947** (PTO-892 ref. **H**). Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a method of preventing attachment of cells to a solid support or other medical device by prior coating of the surface or device with N,O-carboxymethylchitosan.

The disclosure is objected to because of the following informalities:

At page 1, lines 7-9, the application cited is now a US patent. Applicant is respectfully requested to update the information in the noted portion of the disclosure to reflect this change in status.

Incorporation by reference of essential material by reference to a foreign application or a foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by applicant, or a practitioner representing applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

In each of the above cases, the incorporations are of the complete document, and fails to properly point out the particular portions of the US patent(s) being incorporated; see MPEP §608.01(p)(1)(A) noting *In re de Seversky* and in the same paragraph (column 2 of p. 600-769, August 2001 edition) the instruction which reads as follows: “[p]articular attention should be directed to specific portions of the referenced document wherein the subject matter being incorporated may be found.”

In addition, each of the above incorporations represents a failure to provide specific disclosure of how to make and/or use. Therefore, the above citations of the *Hawkins* decisions continue to apply to all incorporations by reference.

The attempt to incorporate subject matter into this application by reference to prior art at page 5 at lines 17-18 and page 8, lines 4-5 is improper because applicant has failed to follow the guidance of the *Hawkins* decisions noted supra. Examiner notes that the patent being incorporated may be incorporated without objection in the discussion in the “Background” portion of the specification.

Appropriate correction is required.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

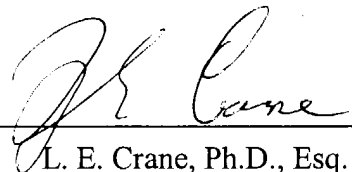
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec  
07/07/2004

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.  
Primary Patent Examiner  
Technology Center 1600